

## CLAIM OBJECTIONS

Claims 1 and 7 were objected to because of periods. The applicant has deleted the periods as suggested by the examiner and inserted underlined semicolons for the periods. Claim 10 was objected to because of the term “further.” This term has been lined through indicating a deletion.

## CLAIM REJECTIONS

Claim 1 was objected to because of the term “soft.” It has been deleted. Claim 3 was rejected because of the terms “easily” and “quickly.” These terms have been deleted. Claim 10 was rejected because of the term “quickly” which has been deleted. In Claims 3 and 10 the terms “hook and loop, Velcro-like tape attachment” was objected to because of the terms “Velcro-like.” “Velcro-like” has been deleted. Claim 8 was objected to because of the term “sized.” Claim 8 has been appropriately amended. Finally, Claim 12 was amended to depend on Claim 10.

## CLAIM REJECTIONS - 35 U.S.C. 103

Claims 1 and 3-10 were rejected under 35 U.S.C 103(a) as being unpatentable over Vinci US Patent # 5,542,121 in view of Gabriele et al, US Patent # 4,030,719, Tari US Patent # 4,662,366. Applicant has previously responded to the use of the Vinci ‘121 and Tari ‘366 as is prior art for applicant’s invention. Applicant incorporates by reference arguments made previously and specifically incorporates arguments made in the appeal in this matter and will not repeat those arguments here, but alleges them by reference.

Examiner has added new prior art not previously raised, Gabriele US Patent # 4,030,719. Gabriele is a foam insert contoured with a cavity designed to restrain a child with restraining straps made from a foam and fabric combination and a plastic base. Examiner states that “it would have been obvious to one having ordinary skill in the art of patients’ supports at the time the invention was made to make the one piece pad of Vinci ‘121 a foam pad as taught by Gabriele et al ‘719 to increase the comfort of the pad.” Applicant respectfully traverses this conclusion of the examiner. Gabriele does not teach a one piece foam pad, but teaches a multi-piece combination of foam, plastic, and fabric used as an immobilizing device. The Tari and Vinci patents are also patient immobilizing devices. They are not devices designed to protect the patient’s arms from outside

pressure and stretching injury. There is no indication in any of these patents that the device is or can be used during an operative procedure to secure and protect the patient's arms from injury from pressure or gravity. Applicant respectfully suggests the examiner has used the applicant's own teaching as a blueprint for a hindsight reconstruction, picking and choosing from disparate prior art which is not used for the same purposes as the applicant's invention, to construct a combination to hold applicant's invention obvious. A hindsight reconstruction is prohibited.

Additionally, as now amended, applicant's invention requires a preperforated tear-a-way foam portion on at least one of the arm supports. Applicant respectfully suggests to the examiner that none of the prior art cited by the examiner has such a feature, nor suggest any reason of the desirability of such a feature. Consequently, applicant's modification of the claims renders moot the examiner's combination under Section 103.

Additionally, applicant has added method claims. Neither Tari, Vinci, nor Gabriele together or in combination teach a method protecting an operative patient's arms from stretch or pressure injuries by using a one piece foam pad with a central portion, with arm section folded around the upper and lower sections of patient's arms, thus providing securing the patient's arms in proximity to the patient's body while also providing a foam barrier between the patient and outside pressure from operating room personnel. Consequently, neither in singly nor in combination do the prior art references raised by the examiner anticipate or render obvious the applicant's methods claims. Additionally, new method Claim 14 provides the feature of a preperforated tear-a-way portion which again is not disclosed or suggested by any of the prior art raised by the examiner.

#### Objective Evidence of Nonobviousness

It has long been accepted law that evidence of secondary considerations may be evidence of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). These include such matters as commercial success, long felt but unmet needs, acceptance in the field, and so on. As objective evidence of nonobviousness, Applicant attaches and incorporates by reference herein four declarations and accompanying exhibits.

The first declaration, attached as Exhibit A1 , with accompanying exhibits A2 and A3 is a declaration of Frank Forrest Humbles, the inventor in this case, with A2 his curriculum vitae, and A3 a printout showing sales of the invention being sold under the trade name of "Lap Wrap." Dr. Humbles is a board certified anesthesiologist. His declaration establishes that there was a long felt, but unmet need, in the market place for a simply used and deployed radiolucent device to protect a patient's arms during an operative procedure. Previous devices which were primarily designed for restraining patients were inadequate to meet the needs that Dr. Humbles recognized and met with his invention. The device is simple enough that it can be made and used as a disposable device. It is simple and easy to use and provides protection not only for the arms of the patient, positioning them in proximity to the patient's torso, but also provides a cushion between the patient and operating room personnel. The device with its tear-a-way portion makes it easy to place IV lines. These declarations establish a long felt, but unmet need, and the commercial success of the device where thousands have been sold.

The second declaration of that of Thomas Holt who is a Certified Registered Nurse Anesthetist. Mr. Holt's declaration is attached as Exhibit B and curriculum vitae is attached as Exhibit B1. CRN Holt's declaration establishes that Dr. Humbles' invention, the Lap Wrap, meets an important need for positioning and protection of the patient's extremities. CRN Holt's declaration states that he has been in practice for 26 years and this is the safest and most easily used arm positioning device and it is the only one of its kind he has seen in an operating room.

The third declaration is from Dr. Paul L. Sasser who is a general vascular surgeon. This declaration and curriculum vitae are attached as exhibits C and C1. Dr. Sasser's declaration establishes that the Lap Wrap device meets important needs for a patient's safety to protect a patient's arms while also allowing easy access to the arm for nerve monitoring and vascular access. As Dr. Sasser puts it the Lap Wrap is on his "needs card for all my head and neck surgery as well as laparoscopic surgeries."

The fourth declaration, Exhibits D , is from Dr. William Mills, a board certified orthopedic surgeon. Dr. Mills' declaration establishes the Lap Wrap met a long felt, but unmet need for a

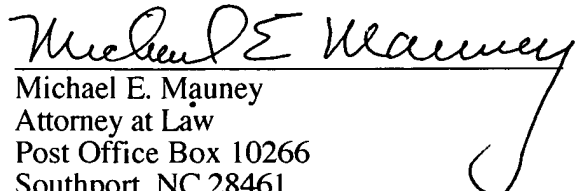
device to protect a patient's arms, but also to allow easy access during different kinds of surgery. Dr. Mills' declaration states he has used the Lap Wrap for years and recommends it to other spine surgeons as well as using it himself. Dr Mills C.V. is attached as exhibit D1

These four declarations fully establish both commercial success and a long felt, but unmet need, for a patient arm positioning device that positions the arms in a safe, comfortable position during an operative procedure, but also protects the patient's arms from pressure generated by operating room personnel leaving on on standing in proximity to a patient's arms. Both commercial success and a long felt, but unmet are established objective indices of non-obviousness.

## CONCLUSION

The applicant has responded to the claim objections and §112 rejections by amending the claims in ways it is believed to overcome these formal requirements. Applicant has responded to the § 103 rejections by appropriate argument and by pointing out that the claims as amended, including the new method claims, are non-obvious over the prior art cited by the examiner. Finally, the applicant has attached objective evidence of non-obviousness that should be sufficient to overcome the examiner's assertions of obviousness absent supporting evidence for the examiner's conclusions. Consequently, it is believed that all claims are now in a condition for allowance and the same is respectfully requested.

This the 11 day of August, 2010.

  
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